4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0164]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry on Safety Labeling Changes; Implementation of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Draft Guidance for Industry on Safety Labeling Changes; Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Draft Guidance for Industry on Safety Labeling Changes; Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act--(OMB Control Number 0910-New)

This draft guidance provides information on the implementation of section 901 of the Food and Drug Administration Amendments Act of 2007, which authorizes FDA to require certain drug and biological product application holders to make safety related labeling changes based upon new safety information that becomes available after the drug or biological product is approved under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) or the Public Health Service Act. FDA plans to request safety labeling changes by sending a notification letter to the application holder. Under section 505(o)(4)(B) of the FD&C Act (21 U.S.C. 355(o)(4)(B)), the application holder must respond to FDA's notification by submitting a labeling supplement or notifying FDA that the applicant does not believe the labeling change is warranted and submitting a statement detailing the reasons why the application holder does not believe a change is warranted (a rebuttal statement).

The submission of rebuttal statements may result in the collection of information that is not already approved by OMB. Based on FDA's experience thus far with safety labeling changes requirements under section 505(o)(4) of the FD&C Act, FDA estimates that approximately six application holders will elect to submit approximately one rebuttal statement each year and that each rebuttal statement will take approximately 6 hours to prepare.

In addition, in the draft guidance, the Agency states that new labeling prepared in response to a safety labeling change notification should be available on the application holder's Web site within 10 calendar days of approval, which may result in the collection of information that is not already approved by OMB. FDA estimates that approximately 197 application holders will post new labeling one time each year in response to a safety labeling change notification and that the posting of the labeling will take approximately 4 hours to prepare.

In the Federal Register of April 13, 2011 (76 FR 20686), FDA published a 60-day notice requesting public comment on the draft version of this guidance. None of the comments we received pertained to the information collection provisions.

FDA estimates the burden of the collections of information that have not already been approved by OMB is as follows:

Table 1.--Estimated Annual Reporting Burden[1]

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Rebuttal statement	6	1	6	6	36

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Third-Party Disclosure Burden[1]

Type of Submission	No. of Respondents	Annual Frequency per Disclosure	Total Annual Disclosures	Hours per Disclosure	Total Hours
Post approved labeling on application holder's Web site	197	1	197	4	788

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

This draft guidance also refers to previously approved collections of information. Specifically, the draft guidance describes: Labeling supplements for new drug applications, abbreviated new drug applications, and biologics license applications submitted under 21 CFR 314.70, 314.71, 314.97, and 601.12, and the content and format of prescription drug labeling submitted under 21 CFR 201.56 and 201.57. These collections of information are subject to review by OMB under the PRA and are approved under OMB control numbers 0910-0001, 0910-0338, and 0910-0572. Section V of the draft guidance refers to the guidance entitled "Formal Dispute Resolution: Appeals Above the Division Level," which describes collections of information approved under OMB control number 0910-0430.

Dated: November 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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